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September 21, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Comments Regarding Institutional Review Boards: Docket No. 98N-0339

Dear Dockets Management Branch:

We would like to thank the Food and Drug Administration for requesting comments on means by which the FDA can help IRBs meet their regulatory responsibilities at the September 8, 1998, public meeting in Bethesda, Maryland. Western Institutional Review Board (WIRB®) is an independent IRB founded in 1968. WIRB provides IRB services for independent investigators, is the IRB of record for several institutions, and serves as part of the University of Rochester's IRB system. We would like to submit our recommendations on how the FDA can help IRBs to meet their regulatory requirements, and on how the current FDA human subject protection system can be improved. The recommendations in this letter are the opinion solely of WIRB, and are not meant to represent the views of any other IRB or organization.

A. Recent Changes in the U.S. Research Environment

Biomedical research has changed significantly since the IRB regulations were first implemented. At that time, most clinical trials involving human subjects were federally-funded and conducted within a single institution, by a single investigator. However, due to a number of factors, including an increase in regulatory requirements for premarket clinical testing, the number of research studies funded by private sources has increased dramatically. These factors have encouraged medical clinics and physicians in private practice to participate in clinical research. Moreover, primarily because of federal clinical testing requirements for new products, clinical trials, especially industry-funded ones, now focus on multi-site studies involving thousands of human subjects. Without doubt, this increase in research conducted at multiple sites has allowed a greater understanding of the benefits and risks of a drug or device before marketing, but it has also left certain parts of the FDA human subject protection system out of date.

B. Recommendations for Improving the Current System

While there is no indication that the current FDA regulatory system for the protection of human subjects has resulted in harm to research subjects, because of the dramatic changes in the

research environment it is appropriate to reevaluate the system at this time. WIRB believes that the current FDA regulations and oversight of IRBs can be improved. To this end, we submit the following recommendations:

IRB Registration

WIRB recommends that the FDA implement IRB registration. At present, FDA lacks basic information on the existence, location, and make-up of IRBs, and must rely on IRB information that is provided by sponsors or investigators in their applications to FDA. WIRB believes that requiring such basic information would help to improve protection of human subjects by allowing the agency to manage its oversight efforts more effectively and to more easily communicate with IRBs.

Information Sharing

WIRB strongly recommends better regulatory support for "information sharing" among the various parties in clinical research. There have been situations where certain sponsors or investigators were displeased with an IRB's review, and have gone to another IRB without disclosing the previous IRB review. While the majority of sponsors and investigators have demonstrated integrity during the IRB review process, WIRB believes that it is important that these parties be obligated to disclose to subsequent IRBs any prior disapprovals of the research.

Further, so that an IRB can effectively monitor the progress of research studies, copies of all FDA inspection reports concerning clinical studies which the IRB has approved should automatically be provided to the reviewing IRB. Currently, IRBs must rely on investigators to provide copies of FDA inspection reports, or utilize the Freedom of Information System if and when the IRB learns the investigator has been audited.

Structure and Education of the Board

WIRB strongly recommends that IRBs should include more non-scientific and non-institutional members. WIRB highly values the important role that these members play in protecting human subjects, and believes that present regulations requiring merely one non-scientific member and one non-institutional member are not adequate.

WIRB also strongly recommends increased board member training. IRB members need initial and continuing education to understand and stay current with the complex scientific, regulatory, and ethical issues in today's research environment. WIRB also supports an increase in investigator training, both inside and outside of institutions. There are few educational resources available for investigators and this contributes to the problem of investigator non-compliance with regulations.

Reforms to the Adverse Event Reporting System

One of the largest and most inefficient drains on IRB resources is the current adverse event reporting system. Twenty-one CFR §§ 312.50 and 312.55(b) require the sponsor to report adverse effects to the investigators, while 21 CFR §§ 312.53(c)(1)(vii) and 56.108(b)(1) require

the investigator to report to the IRB any unanticipated problems involving risks to subjects. The result is that each IRB receives copies of the same adverse event report from each investigator involved in the study. In large multi-site studies, this can involve hundreds of copies of the same report being sent to a single IRB. FDA could require the sponsor to submit a summarized safety report to each IRB, thus drastically reducing the number of copies of the same safety report sent to the IRB. This would enhance subject protection by allowing the IRB to more efficiently use its resources.

Common Policy Shared by FDA and NIH/OPRR

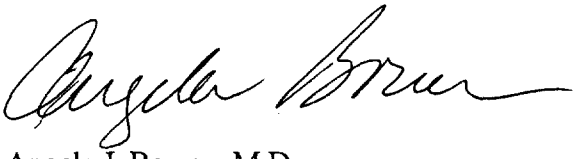
We strongly support the concept of a "shared" policy between FDA and NIH/OPRR in oversight of IRBs. Regulatory mechanisms employed by FDA and NIH/OPRR vary. FDA oversight of IRBs is included in the process of evaluating the safety and efficacy of drugs, devices, and biologics. Its approach is more compliance-based, focusing on inspection of IRB research sites. In contrast, NIH/OPRR oversight of IRBs focuses on assurances.

Each of these systems incorporates valid oversight tools. However, we believe that similar oversight policies and close collaboration would strengthen the protections to human subjects. Moreover, a common policy would result in a more efficient regulatory scheme that would be advantageous to both the federal government and to IRBs. We believe that a shared policy between FDA and NIH/OPRR will improve the ability of IRBs to comply with federal policies, regardless of whether the research protocol is regulated by NIH/OPRR or by FDA. We also recommend that NIH/OPRR and FDA involve other departments in the Department of Health and Human Services, as well as non-federal parties such as IRBs, sponsors, and clinical investigators, in development of a shared policy.

C. Conclusion

WIRB would like to thank the FDA Docket Management Branch for this opportunity to offer recommendations on the improvement of the FDA oversight of IRBs and the human subject protection system. Please feel free to contact us if we may be of any assistance.

Sincerely,



Angela J. Bowen, M.D.
President

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